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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,573	06/28/2000	Robert De Leys	CDS-222	5829

7590 10/02/2002

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EXAMINER
PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/605,573	DE LEYS ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 31 May 2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 1-3 and 5-15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Office Action

Status of the Claims

1. Applicants' election with traverse of Group II (claim 4), in Paper No. 9 is acknowledged. Applicants traverse and submit that Groups II-VII should be examined concomitantly since they do not pose a serious burden on the examiner. Applicants' are reminded that establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The following items adduce a p*rima facie* showing of burden:

1) The inventions of Groups I-VIII display both separate classifications and a separate status in the art as set forth in Paper No. 5.

2) The inventions of Groups I-VIII are directed towards different inventive concepts. As previously set forth, the inventions are distinct, each from the other because of the following reasons:

> 3. Inventions I-III, V, and VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified groups is directed toward a structurally different product or composition with different attendant immunological, biochemical, and physical activities. Separate searches will also be required for each group. Therefore, each invention is clearly drawn toward a different inventive entity.
>
> 4. Inventions IV, VI, and VII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified methods is directed toward a different scientific objective (e.g., protein production, antibody capture assay, antigen capture assay) that employs materially different reagents and protocols. Each group will necessitate a separate search. Accordingly, each invention is clearly drawn toward a different inventive concept.

5. Inventions I and VII, II and IV/VI, III and VI/VII, V and IV/VI/VII, and VIII and IV/VI/VII, respectively, are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, none of the products identified in Groups I, II, III, V, and VIII are required to practice the methodologies of the corresponding groups, and the corresponding groups neither require nor use their respective peptides. Therefore, each invention is clearly drawn toward a different inventive entity.

6. Inventions I and VI, II and VII, and III and IV, respectively, are each related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ¶ 806.05(h)). In the instant case, each of the products identified can be employed in materially different processes. For instance, the peptide of Group I can be utilized as an immunogen to produce immunological reagents, the antibody of Group II can be utilized in affinity purification procedures, and the nucleic acids of Group III can be utilized as probes for the detection of virus.

7. Inventions I and IV are related as product made and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different products, or (2) the product as claimed can be made by another and materially different process (M.P.E.P. ¶ 806.05(f)). In the instant case, the peptide of Group I can be prepared by a materially different process such as solid-state peptide synthesis.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, requirement for independent searches, and recognized divergent subject matter, restriction for examination purposes as indicated is proper. **Applicants are required under 35 U.S.C. § 121 to elect a single group for prosecution on the merits. Applicants are further advised that a single peptide should also be elected where appropriate.** Because of their unique amino acid sequence, each peptide constitutes an independent and distinct invention. Separate searches will be required for each peptide. Applicants are also reminded that the claims should be amended, if necessary, to reflect the election.

Accordingly, each invention will generate unique issues regarding novelty, patentability, and enablement.

3) Since the inventions disclosed *supra* are directed towards

patentably distinct material, a search for one invention would not necessarily result in the identification of art that is concomitant with that required to address the issues generated by the other inventions. Applicants arguments have been thoroughly considered but are not deemed persuasive for the reasons set forth *supra* and in the original restriction requirement (Paper No. 5). **The requirement is still deemed to be proper and is therefore made FINAL.** Claims 1-3 and 5-15 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 112, Second Paragraph

2. Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants are reminded of the restriction requirement set forth in Paper No. 5. The claim language should be amended to reflect this requirement (i.e., an antibody that binds specifically to a peptide consisting of SEQ ID NO.: 69). The claims are further vague and indefinite for failing to clearly set forth the salient characteristics and features of the claimed antibody. For instance, does the antibody bind specifically to an epitope present in the peptide having SEQ ID NO.: 69 or does it recognize other epitopes outside of this region? Applicants should clearly and unambiguously set forth the salient binding and other functional characteristics of the claimed antibody.

Correspondence

3. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

4. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

5. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2002